MONOGRAPH

Valaciclovir Monograph - Paediatric

Scope (Staff):	Medical, Pharmacy, Nursing,
Scope (Area):	All Clinical Areas (Perth Children's Hospital)

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this DISCLAIMER

⚠ HIGH RISK MEDICINE ⚠

QUICKLINKS

DRUG CLASS

Guanine analogue and prodrug of aciclovir.[1]

Valaciclovir is a High Risk Medicine.

INDICATIONS AND RESTRICTIONS

- Valaciclovir is used in the treatment and prevention of herpes simplex virus (HSV), varicella-zoster virus (VZV) and cytomegalovirus (CMV).[1]

Oral: Monitored (orange) antiviral

- If the use is consistent with a standard approved indication, this must be communicated to ChAMP by documenting that indication on all prescriptions (inpatient and outpatient).
- The ChAMP team will review if ongoing therapy is required and/or if the order does not meet ChAMP Standard Indications
- If use is not for a standard approved indication, phone approval must be obtained from ChAMP before prescribing.

CONTRAINDICATIONS

- Hypersensitivity to valaciclovir, aciclovir or any component of the formulation.[1-3]

PRECAUTIONS

- Use with caution in renal impairment due to increased risk of neurological adverse effects, dose adjustment is required.[1]
- CNS adverse effects have been reported in children with and without renal impairment receiving high dose therapy. These adverse effects include agitation, hallucinations, confusion, delirium, seizures and encephalopathy.[2]
- Thrombotic thrombocytopenic purpura (TTP) and haemolytic uraemic syndrome (HUS) have been associated with high dose, prolonged use of valaciclovir in immunocompromised patients (e.g. post-transplant or HIV positive patients).[2] Treatment with valaciclovir should be ceased immediately if clinical signs, symptoms and laboratory abnormalities consistent with TTP/HUS occur.[2]

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- Valaciclovir 500mg tablet

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

- Although valaciclovir is not licensed for use in children in Australia it is thought to be a safe alternative to aciclovir as it is a prodrug of aciclovir and may be preferred for its more convenient dosing schedule and greater bioavailability.[2, 4] Valaciclovir is licensed for use internationally in children >2 years.[4]

Neonates and children <3 months of age:

Valaciclovir is not routinely used in neonates or children < 3 months of age and has limited data on use in children under 2 years of age. Contact the Infectious Diseases or Clinical Microbiology service for advice. Aciclovir is preferred in those <3 months of age.

Refer to: Aciclovir Monograph – Paediatric **OR**

KEMH Neonatal Medication Protocol - Aciclovir

Prophylaxis:

Herpes Simplex Virus (HSV) or Varicella Zoster Virus (VZV) (immunocompromised):

- Children <3months – Aciclovir preferred, refer to Aciclovir monograph - Paediatric
- Children ≥ 3 months and <40kg: 250mg twice daily.[5, 6]
- Children and adolescents ≥ 40kg: 500mg twice daily.[5]

Herpes Simplex Virus (HSV) or Varicella Zoster Virus (VZV) (immunocompetent):

- Children <3months – Aciclovir preferred, refer to Aciclovir monograph - Paediatric
- Children ≥ 3 months: 10mg/kg/dose (to a maximum of 500mg) once daily.[4, 7]

Treatment:

Immunocompromised children:

Herpes Simplex Virus (HSV) or Varicella Zoster Virus (VZV):

- In majority of cases, initial IV therapy is required with aciclovir for immunocompromised patients. Oral switch to valaciclovir may be considered following improvement to complete a total duration of 7 to 14 days.[4]
- Children ≥ 2 years: 20mg/kg/dose (to a maximum of 1000mg) three times a day - discuss duration of therapy with Infectious Diseases physician.[4]

Immunocompetent children:

Varicella infection (chicken pox and shingles):

- Children with pre-existing skin disease (e.g. eczema) require antiviral therapy due to greater risk of severe varicella including extensive cutaneous varicella and complications of varicella (e.g. pneumonia, encephalitis and hepatitis).[4] Children without significant pre-existing skin disease do not require antiviral therapy for varicella as the benefits of treatment are only marginal.[8]
- Children ≥ 3 months (immunocompetent): 20mg/kg/dose (to a maximum of 1000mg) three times daily initiated within 24 hours of rash onset.[2, 8]
- Treatment should continue for five (5) days for chicken pox and seven (7) days for shingles.[4]

Severe primary gingivostomatitis:

- Children ≥ 3 months: 20mg/kg/dose (to a maximum of 1000mg) 12 hourly for 5 to 7 days.[8]

Recurrent Herpes Simplex (treatment) - Infrequent and severe recurrences:

- Adolescent 12-18 years: 2g for two doses taken 12 hours apart at earliest symptoms of a cold sore in selected patients (i.e. with severe infection).[1, 4, 8, 9]
- Contact Infectious Diseases or Clinical Microbiology consultant for use in children below 12 years old for this indication.

Renal impairment:

- eGFR calculator (Google Chrome®)
- Dosage adjustment may be required in cases of impaired renal function (with creatinine clearance of less than 50mL/min) due to increased risk of neurological adverse effects.[1, 4]

The below dose adjustments are based on an initial treating dose of 20mg/kg/dose given three times a day. If starting dose is lower as per above dosage section, contact the Ward Pharmacist to discuss dose adjustments.

- CrCl ≥50mL/min: Normal dose
- CrCl 30-49mL/min: 20mg/kg/dose given twice daily
- CrCl 10-29mL/min: 20mg/kg/dose given once daily
- CrCl <10mL/min: 10mg/kg/dose given once daily.[10]

Hepatic impairment:

- No dose reduction is required in patients with hepatic impairment.[10]

ADMINISTRATION

- May be administered without regard to food intake.[2, 10, 11]
- The tablets may be crushed, however they have a very unpleasant taste.[11]

  Patients should be instructed to drink plenty of fluids whilst undergoing treatment with valaciclovir.[1, 3]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

- Not applicable

MONITORING

- Hepatic, haematological and renal function including urea and electrolytes should be monitored with prolonged therapy (longer than 7 days).[2, 10, 12]

ADVERSE EFFECTS

As aciclovir is the active metabolite of valaciclovir adverse effects seen with aciclovir are likely to occur with valaciclovir.[1]

Common: diarrhoea, skin reactions, photosensitivity reactions, dizziness, nausea, vomiting, headache and fatigue.[1, 13]

Infrequent: agitation, vertigo, renal impairment, confusion, dyspnoea, haematuria, tremor.[1, 13]

Rare: neurological effects (more likely in patients with renal impairment or taking high doses include; coma, encephalopathy, psychotic symptoms, delirium, seizure), leucopenia, thrombocytopenia, tremor, ataxia, thrombotic thrombocytopenic purpura, haemolytic uraemic syndrome and multi-organ hypersensitivity syndrome, angioedema, ataxia.[1, 2, 13]

STORAGE

- Valaciclovir tablets should be stored below 25°C.[3, 12]

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. Clinical Pharmacology), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

Please note: The information contained in this guideline is to assist with the preparation and administration of **valaciclovir.** Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

Antimicrobial Stewardship Policy

ChAMP Empiric Guidelines and Monographs

KEMH Neonatal Medication Protocols

References

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